REMARKS

In view of above amendments and the following remarks, the Examiner is requested to allow Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57, and 72-74 the only claims pending and under examination in this application, after entry of the above amendments.

Claim 1 has been amended to recite the element of Claim 30. Additionally, Claims 2-4, 12 and 23 have been amended to clarify the claim language. Support for these amendments may be found throughout the specification and claims as originally filed. Claim 30 has been cancelled. Claim 100 has been added. Support for Claim 100 may be found at paragraph 30. Accordingly, no new matter has been added.

As no new matter has been added by way of these amendments, their entry is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 2-4 and 23-24 have been rejected as allegedly being indefinite. Claims 2-4 and 23 have been amended, thereby rendering this rejection moot. The Applicants, therefore, respectfully request that this rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Freidman et al. (WO 99/06030).

The Applicants disagree to the extent that this rejection may be held to apply to the claims as amended. The Applicants contend that a *prima facie* case of obviousness has not been established with respect to the amended claims because

amended Claim 1, and the claims dependent there from, is directed to a flavored dosage form that comprises a lozenge. The lozenge includes a sustained release wet matrix of ethylcellulose and a flavoring agent. The flavoring agent is selected from essential oils, constituents of essential oils, and mixtures thereof. Further, in an aqueous environment, the matrix gradually releases the flavoring agent over a time period of at least 15 minutes. Accordingly, an element of Claim 1, as amended, is a lozenge that includes a wet matrix of ethylcellulose and a flavoring agent.

According to the M.P.E.P. § 706.02 (j), to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

As set forth above, Claim 1 has been amended to incorporate the element of Claim 30 therein. Specifically, Claim 1 has been amended such that it is now directed to a lozenge. As Claim 30 was not recited in this rejection, this amendment should be sufficient to overcome this rejection. Accordingly, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Furthermore, as set forth above, an element of the rejected claims is a lozenge that includes a sustained release wet matrix of ethylcellulose and a flavoring agent. According to the Applicants specification, by a "'wet' matrix is meant a matrix that contains a liquid phase that represents a sufficiently large fraction of the matrix to provide a discernibly wet or sticky surface, and/or a soft and rubbery consistency."

With respect to the claimed "wet matrix" the Office acknowledges that Freidman does not disclose a "wet matrix," but asserts that "in the presence of the essential oil or extract (when a liquid) it can be concluded the mixtures are wet." See page 5, of the Office Action.

The Applicants respectfully disagree and contend that Friedman actually teaches away from a lozenge that includes a "wet matrix," because Friedman discloses the following:

> However, it should be noted that one ingredient in the tablets of the present invention can be a herbal extract, which is itself a liquid. The addition of the herbal extract to the tablet presents a challenge, since large amounts of liquid are not well incorporated into tablets, which are dry solids. This problem is solved in one of two ways.

See page 5, lines 25-28.

In view of the above, Friedman teaches away from the claims because Friedman discloses that the refernced tablets are "dry solids," and thus, not a "wet matrix." Accordingly, one of skill in the art would not look to Freidman for a teaching of the use of a lozenge that includes a wet matrix as is presently claimed. Thus, for this reason alone, the Applicants respectfully request that this rejection be withdrawn.

Further still, as acknowledged by the Office, Freidman is directed to a slow release tablet, not a lozenge. In fact, when viewed as a whole, Friedman actually teaches away from the use of a lozenge.

According to the MPEP § 2145, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness.

Specifically, Freidman teaches:

> Although currently available troches and lozenges have the advantage of enabling medication to be in prolonged contact with the mouth and throat, such tablets still have a number of disadvantages. First, although troches and lozenges do not dissolve immediately, the rate of release of medication is still relatively rapid, on the order of about 15 minutes for total release. Second, these dosage forms have not been specifically tested with herbal medications, or medications derived from botanical materials. Thus, the efficacy of these dosage forms with herbal medications is unknown. Hereinafter, the term "herbal medication" refers to a medication

See page 1, lines 22-28.

In view of the above, Freidman teaches away from the claims because Friedman discloses that lozenges have a relatively rapid release rate and are untested with respect to herbal medications. Accordingly, one of skill in the art would not look to Freidman for a teaching of the use of a lozenge as a suitable dosage form as is presently claimed. Thus, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Therefore, in view of the amendment to Claim 1, Freidman does not teach or suggest all the elements of the rejected claims. Namely, Freidman does not teach or suggest a lozenge that includes a wet matrix of ethylcellulose and a flavoring agent. Freidman does not teach or suggest this because Freidman actually teaches a dry, solid, tablet, and, in fact, teaches away from a lozenge, as claimed. Accordingly, a *prima facie* case of obviousness has not been established because Freidman does not teach or suggest all the elements of the rejected claims. Consequently, the Applicants respectfully request that this rejection be withdrawn.

Claims 1-8, 12-13, 23-25, 30, 46-48, and 72-73 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Alderman et al. (U.S. Patent No. 4,528,125).

As set forth above, an element of the rejected claims is a lozenge that includes a sustained release wet matrix of ethylcellulose and a flavoring agent. The Applicants contend that a *prima facie* case of obviousness has not been established

because Alderman does not teach or suggest a lozenge that includes a sustained release wet matrix.

Rather, Alderman discloses an aqueous dispersion that includes a) cellulose ether, which is dispersed as a plurality of finely divided cellulose ether particles into a continuous aqueous phase, and b) a fragrance that is reversibly diffused in the cellulose ether particles. The Applicants contend that an aqueous dispersion of fine particles that include a fragrance adsorbed thereto is not equivalent to the lozenge containing a matrix as claimed by the applicants. Thus, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Further, the Applicants contend that Alderman does not teach a matrix because Alderman actually teaches away from a sustained release matrix system.

According to the MPEP § 2145, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness.

Specifically, Alderman discloses:

> The sustained release dispersions of this invention possess several advantages over conventional sustained release systems. The flavoring or fragrance is readily diffused into the cellulose ether particles. In contrast to matrix type sustained release systems, the flavoring or fragrance is more uniformly distributed throughout the cellulose ether particles. The physical form of the dispersion of this invention allows for a wide variety of uses not available to conventional sustained release systems. In addition, the compositions of the dispersion
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> See column 6, lines 30-39.

In view of the above, Alderman teaches away from the claims because Alderman discloses that dispersions are advantageous over sustained release matrix systems, such as those instantly claimed by the Applicants, because in a dispersion, as contrasted with a matrix system, the fragrance is more uniformly distributed

therein and the physical form of the dispersion allows for a wide variety of uses that are not available in conventional, e.g., matrix based, sustained release systems. Accordingly, one of skill in the art would not look to Alderman for a teaching of the use of a lozenge containing a matrix as a suitable dosage form as is presently claimed. Thus, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Therefore, in view of the above, Alderman does not teach or suggest all the elements of the rejected claims. Namely, Alderman does not teach or suggest a lozenge that includes a wet matrix of ethylcellulose and a flavoring agent. Alderman does not teach or suggest this because Alderman actually teaches a dispersion of individual cellulose ether particles that have a fragrance adsorbed thereto, and, in fact, teaches away from a matrix sustained release system, as claimed. Accordingly, a *prima facie* case of obviousness has not been established because Alderman does not teach or suggest all the elements of the rejected claims. Consequently, the Applicants respectfully request that this rejection be withdrawn.

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ventouras (U.S. Patent No. 6,183,775).

As set forth above, Claim 1 has been amended to incorporate the element of Claim 30 therein. Specifically, Claim 1 has been amended such that it is now directed to a lozenge. As Claim 30 was not recited in this rejection, this amendment should be sufficient to overcome this rejection. Accordingly, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Further, as set forth above, an element of the rejected claims is a lozenge that includes a sustained release wet matrix of ethylcellulose and a flavoring agent. The Office asserts that Ventouras discloses an ethyl cellulose matrix and a peppermint oil. While Ventouras may disclose a dosage form that includes ethyl cellulose and a dosage form that includes peppermint oil, at no point in time does Ventouras teach or suggest a lozenge that includes a wet matrix that includes both ethylcellulose and

a flavoring agent. Accordingly, Ventouras is deficient in that it does not teach all the elements of the rejected claims and for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Additionally, an element of the rejected claims is a "wet matrix." The Office acknowledges that Ventouras does not teach a "wet matrix." The Office, however, asserts that it would have been obvious for one to have adjusted the ratios of components so as to obtain a dosage form of the desired consistency. See page 7. The Applicants respectfully disagree and contend that Ventouras actually teaches away from a "wet matrix," and thus one would not be motivated to use Ventouras in the manner suggested by the Office.

According to the MPEP § 2145, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness.

Specifically, Ventouras discloses:

> If a buccal delivery system is manufactured only from a mixture of the soluble filler (a) with the swellable polymer (c)—under omission of the insoluble film-forming agent (b)—, by compression, lozenges are obtained that have prolonged release properties but that cause an unpleasant sensation of swelling and gelling in the mouth. Moreover,
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> See column3, lines 51-57.

As can be seen with reference to the above, Ventouras teaches away from a "wet matrix" as recited in the rejected claims because Ventouras discloses the use of a soluble filler, an insoluble film forming agent, and a swellabel polymer so as to produce a controlled release dosage form that is dry, e.g., not gelling. Accordingly, one of skill in the art would not look to Ventouras for a teaching of the use of a lozenge employing a wet matrix as a suitable dosage form as is presently claimed.

Thus, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

Therefore, in view of the above, Ventouras does not teach or suggest all the elements of the rejected claims. Namely, Ventouras does not teach or suggest a lozenge that includes a wet matrix of ethylcellulose and an essential oil. Ventouras does not teach or suggest this because at no point in time does Ventouras disclose a lozenge that includes a wet matrix that includes both ethylcellulose and a flavoring agent, and, in fact, Ventouras teaches away from a "wet matrix," as claimed. Accordingly, a *prima facie* case of obviousness has not been established because Ventouras does not teach or suggest all the elements of the rejected claims. Consequently, the Applicants respectfully request that this rejection be withdrawn.

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 1-7, 10-16, and 23 of copending U.S. Application No. 11/904,420.

The Applicants disagree. Nevertheless, because none of the presently pending claims of either the present application nor the copending '420 application have been allowed, the Applicants respectfully request that this rejection be held in abeyance until one or more claims of either application are found allowable, at which time an appropriate response will be advanced by the Applicant.

New Claims

As indicated above, new Claim 100 has been added. New Claim 100 ultimately depends from Claim 1. Accordingly, for the reasons' stated herein above, new Claim 100 is patentable.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested.

Respectfully submitted,

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